IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	C.A. No. 22-252-JDW
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH, *Counterclaim- Defendants.*	**JURY TRIAL DEMANDED** [redacted] Redacted - Public Version

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF
MOTION TO EXCLUDE EXPERT TESTIMONY

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I. SUMMARY OF ARGUMENT AND NATURE AND STAGE OF PROCEEDINGS

While rejection of expert testimony under *Daubert* is the exception not the rule, certain opinions offered by Moderna's experts contradict governing law so flagrantly that they must be excluded. Dr. Vellturo's damages model flouts clear, controlling precedent concerning both the use of past license agreements and consideration of non-infringing alternatives. Dr. Prud'homme's opinions repeatedly defy legal standards, relying impermissibly on irrelevant evidence and features concededly unclaimed to assert non-infringement and invalidity. And Dr. Anderson admits openly that his obviousness opinions are premised on hindsight, which cannot give rise to obviousness. All of this testimony would only misinform the jury and should be excluded.

II. LEGAL STANDARD

The Rules of Evidence limit "the admissibility of purportedly scientific evidence by assigning to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 579-580 (1993). For patent damages, that requires accounting for any "differences in the economic positions of negotiating parties" when relying on past licenses, *Smartsky Networks, LLC v. GoGo Business Aviation LLC*, 2025 WL 2972258, at *9 (D. Del. Oct. 21, 2025), and "accurately reflect[ing] the real-world bargaining" dynamics of the parties, *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp., LLC*, 879 F.3d 1332, 1349 (Fed. Cir. 2018); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1325 (Fed. Cir. 2009).

For all experts, courts "encourage exercise of the trial court's gatekeeper authority when parties proffer, through purported experts, not only unproven science ... but markedly incorrect law." *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996). Rule 702 bars admission of testimony that is contrary to the law. *Sec'y United States Dep't of Lab. v. Nursing Home Care Mgmt. Inc.*, 128 F.4th 146, 162 (3d Cir. 2025).

III. DR. VELLTURO'S DAMAGES OPINIONS SHOULD BE EXCLUDED

Dr. Vellturo's damages opinions are rife with methodological errors that render it inadmissible. Dr. Vellturo did not analyze "what it would have been worth to [Moderna], as it saw things at the time [May 31, 2020], to obtain the authority to use the patented technology," which is "a key inquiry in the [reasonable royalty] analysis." *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333, 1340 (Fed. Cir. 2025) (en banc). Instead, while purporting to ground his rate in 13 so-called "Historical Comparable Licenses" entered by Plaintiffs, Ex 1 (Vellturo) ¶ 185,[1] what Dr. Vellturo did was mix Moderna's blockbuster sales figures with fixed-sum payments drawn from licenses for preclinical products at a research stage, without *any* effort to reconcile the starkly different circumstances. This directly contradicts controlling precedent and compels exclusion.

The quantitative veneer of Dr. Vellturo's opinion also averts the actual bargaining dynamics that a hypothetical negotiation analysis must consider. Moderna knew about Plaintiffs' patents for years and thus concluded that it had "***strong business reasons***" to seek alternative LNP formulations. Ex 2 (2017 Hoge Email). Moderna's effort to design around Plaintiffs' patents failed, leaving it no choice but to use Plaintiffs' technology when it needed to launch a COVID-19 vaccine in record time. In response to this dynamic, Dr. Vellturo buries his head in the sand, deeming it not legally relevant based on law that applies only to the specific and limited circumstance of Standard Essential Patents, which the patents-in-suit are not. He also claims to have accounted for the effect of non-infringing alternatives, indirectly, by considering Plaintiffs' 13 licenses with other companies—although he made no attempt to show that the other counterparties had the same set of supposed non-infringing alternatives and valued them the same as Moderna did. His legally flawed treatment of a core issue separately merits exclusion.

[1] All highlighting in the exhibits has been added. Unless otherwise noted, all emphasis is added, and internal citations and quotations are omitted.

A. Dr. Vellturo's "Effective Royalty" Calculation Violates Controlling Law

Dr. Vellturo squarely violated governing law by obtaining a royalty rate by converting lump-sum payments (the numerator) into running royalties using *$14 billion of Moderna's sales*, instead of the sales expectations of those 13 licensees, as the denominator. Ex 1 (Vellturo) ¶ 217. The law is clear: lump-sum payments cannot be converted to a running royalty without "relevant sales figures to verify whether the lump sums corresponded to a particular unit-based rate." *EcoFactor*, 137 F.4th at 1345-46. Those sales figures must belong to the particular licensee, *not* the defendant. *Baltimore Aircoil Co. v. SPX Cooling Techs. Inc.*, 2016 WL 4426681, at *25 (D. Md. Aug. 22, 2016) (excluding conversion of lump sum because it used defendant's sales).

Dr. Vellturo's brazen violation of this precedent mandates exclusion. All 13 licenses Dr. Vellturo relies on contain a mix of lump-sum milestone payments and running royalties. Ex 1 (Vellturo) ¶¶ 93-157, 185. The milestones are central to the licenses, as all 13 were negotiated before clinical trials, when it was uncertain whether *any* commercial sales ever would result. Ex 3 (Zorn Tr.) 200:1-19; Ex 4 (Vellturo Tr.) 158:8-12, 159:2-20. Importantly, many of the licenses relate to diseases different from COVID-19, and thus different markets. Ex 1 ¶¶ 93-157. Yet when Dr. Vellturo converted the milestones in the 13 agreements to effective royalty rates, he used the sales of one of the best-selling drugs in history—Moderna's COVID-19 vaccine—as the denominator. The result of that equation is plainly irrelevant and highly misleading. Because (for example) a [redacted] milestone is a far higher percentage of $100 million in sales than $14 billion in sales, his approach artificially makes the royalties in the agreements seem much smaller.

This is not a matter that can be addressed on cross-examination. By attempting to convert lump-sum milestones to royalty rates without regard to any facts or data about those particular licensees' expectations, Dr. Vellturo committed the precise error that the *en banc* Federal Circuit held compelled exclusion in *EcoFactor*. There, the expert converted lump sum payments to a

running royalty without "access to sales data" for the licensed products and without "data from which any market predictions were made regarding past or projected sales for any of the licensees." 137 F.4th at 1344. The court held that, without sales figures or projections from the licensees, the expert's analysis "unravels" and must be excluded. *Id.* at 1346. *EcoFactor* is on all fours with Dr. Vellturo's error, and it is no outlier: Courts regularly hold that converting lump-sum payments into a running royalty requires "some basis for comparison"—to derive a percentage rate, there must be an actual or projected sales volume. *Whitserve, LLC v. Comp. Packages, Inc.*, 694 F.3d 10, 30 (Fed. Cir. 2012); *Baltimore Aircoil*, 2016 WL 4426681, at *25; Ex 4 (Vellturo Tr.) 181:14-18 ("to compute an effective royalty rate … one needs to project out an expected royalty base").

A basis for comparison is precisely what Dr. Vellturo lacked. As he admits, he did not use "any actual data" or any information about the sales expectations for the 13 licenses. Ex 4 (Vellturo Tr.) 188:16-189:8. This is not only legal error, it is also inexcusable because Dr. Vellturo ignores the estimates that were available for at least one licensee, Ex 5 (Lawton Reply) ¶¶ 191-198, and Moderna never sought third-party discovery in connection with the others.

Dr. Vellturo "provides no justification" for why using Moderna's sales figures to fill the gap of Moderna's own making "is a reliable methodology." *Baltimore Aircoil*, 2016 WL 4426681, at *25. When using prior licenses, experts must take "careful account of any economically relevant differences between the circumstances of those licenses and the circumstances of the matter in litigation." *Carnegie Mellon Univ. v. Marvell Tech.*, 807 F.3d 1283, 1304 (Fed. Cir. 2015). Failure to account for such "differences in the economic positions of negotiating parties [is] adequate grounds on which to exclude expert testimony." *Smartsky Networks*, 2025 WL 2972258, at *9.

It is undisputed that there are significant economically relevant differences with respect to the 13 licenses. Dr. Vellturo admits this, opining that the circumstances of the hypothetical

negotiation would differ from the circumstances of the negotiations with "previous licensees to the Patents-in-Suit ... ***as none of those licenses have yet resulted in a successfully commercialized mRNA product, much less one that has had the success of mRNA-1273***." Ex 1 (Vellturo) ¶ 279. The 13 licenses were entered into at a dramatically different stage of development, prior to clinical trials, with no actual sales or knowledge as to whether there ever would be sales. Ex 4 (Vellturo Tr.) 158:8-12, 159:2-22; Ex 3 (Zorn Tr.) 200:14-19. By contrast, as of the hypothetical negotiation date, Ex 1 (Vellturo) ¶ 71, Moderna already had received "Positive Interim Phase 1 Data" for its COVID-19 vaccine, begun its Phase 2 trial, and was nearing the start of Phase 3 trials. Exs 6-7 (Moderna press releases). Moderna had announced receipt of a nearly $500 million federal grant, intended to "accelerate development" of the COVID-19 vaccine "to FDA licensure." Ex 8 (Moderna press release). Dr. Vellturo acknowledges the importance of accelerating Moderna's development, explaining that "time was of the essence, as companies raced to be the first to market in order to slow the spread of the [COVID-19] pandemic and meet the massive demand for a vaccine." Ex 1 ¶ 277. But his analysis makes *no adjustment* to account for these differences in circumstance. Nor does he consider how the disease target would affect sales, despite the fact that almost all of the 13 agreements relate to diseases with far smaller commercial markets than the COVID-19 vaccine, like Wilson's disease, Alpha-1 antitrypsin deficiency, and monogenic liver disorder. *Id.* at ¶¶ 106, 116, 120, 126, 132, 142, 146, 154. And while two of the licensees were developing COVID-19 products, both had a significant disadvantage in development, as their development was well behind that of Moderna and lacked the benefit of being part of the U.S. Government's Operation Warp Speed. Ex 9 (CRS Report). Beyond a summary description of the agreements, Dr. Vellturo's report contains no individualized discussion of the economic circumstances of *any* of the licensees or their potential products. Ex 1 ¶¶ 93-157. And regardless,

it is not enough to "merely *identif*[*y*] such differences," as he had an "obligation to '*account* for such distinguishing facts' in invoking the licenses." *Omega Pats., LLC v. CalAmp Corp.*, 13 F.4th 1361, 1381 (Fed. Cir. 2021). He did not do so.

Dr. Vellturo's failure to consider or account for the economic circumstances of the licenses means his methodology produces unreliable and meaningless data cloaked in a quantitative veneer that will confuse, rather than aid, the jury. The data Dr. Vellturo chose to ignore for the Providence license demonstrates the point. Public reporting and documents produced in discovery show that Providence planned to charge $18 per dose for its vaccine, Ex 10 (CBC News), with expected volumes in May 2020 of 5 million doses, Ex 11 (National Post) which increased to [redacted] doses in 2021, Ex 12 (Providence budget). Thus, rather than the $14 billion in *actual* Moderna revenue Dr. Vellturo used to calculate an effective royalty for Providence, Ex 13 (Vellturo Ex 7.2), Providence's *expectations* at the time of licensing were between 90 and [redacted] million *Canadian* dollars—[redacted]-99% less than Dr. Vellturo's unsupported assumption. Remarkably, Dr. Vellturo claimed he chose not to use this information about Providence's "revenue expectations" because "[i]t wasn't germane to what I was doing." Ex 4 (Vellturo Tr.) 157:14-158:7. But the impact on "what [he] was doing" is clear. Using *Moderna's actual sales*, he calculated an effective royalty of [redacted] for Providence. Ex 13 (Vellturo Ex 7.2). Using *Providence's expectations* would have resulted in rates from [redacted] Ex 5 (Lawton Reply) ¶¶ 191-198.

Dr. Vellturo's only attempt to reconcile his use of Moderna's high sales to calculate royalty rates in preclinical licenses came at his deposition, when for the first time, he claimed his analysis is supported by the best-case-scenario sales volume royalty tiers found in the 13 licenses. Ex 4 (Vellturo Tr.) 152:20-153:12. This post hoc rationalization—absent entirely from his report—does not withstand scrutiny. The evidence about licensee sales projections shows that the inclusion

of high tiers for sales milestones in the agreements did *not* reflect a contemporaneous expectation that sales would reach those levels. *See* Ex 12 ([redacted]; Ex 14 (Vellturo Ex 6). Dr. Vellturo offers no contrary evidence, only unsupported speculation about the meaning of the sales tiers. But even if the agreements' highest tiers *were* evidence of the parties' sales expectations, he neither calculated rates based on these tiers nor explained how they would justify using Moderna's far higher actual sales to calculate effective rates. Dr. Vellturo calculates Moderna's sales as $5.7 billion per year for 2021-22. Ex 13 (Vellturo Ex 7). The annual sales tiers in the 13 licenses vary widely, with top (best case) tiers ranging from [redacted]. Ex 14 (Vellturo Ex 6). Moderna's sales thus were several times higher than the "best case scenario" threshold for most of these licenses. Without any explanation or justification for using Moderna's sales, notwithstanding these differences, Dr. Vellturo's opinions "fail[] to clear the threshold of reliability required by *Daubert*." *Baltimore Aircoil*, 2016 WL 4426681, at *25.

Dr. Vellturo opined that the "effective" royalty rates he calculated using Moderna's sales figures were the "natural central focus" of the hypothetical negotiation exercise, Ex 1 ¶ 422, and the parties would "likely gravitate towards" the royalty rate he calculated from the Providence agreement, *id.* at ¶ 283. The rates he calculates form the basis of both his own royalty opinion and his critique of Plaintiffs' expert Ms. Lawton's royalty opinion. *Id.* at ¶¶ 243-244, 422, 769-770. His calculation was thus "crucial to [his] damages analysis," and the clear flaws compel exclusion of his royalty opinion, as well as his critique of Ms. Lawton's. *EcoFactor*, 137 F.4th at 1346.

B. Dr. Vellturo's "Hold Up" Opinion Is Legal Error

Dr. Vellturo's hypothetical negotiation opinions also are fatally flawed for the independent reason that they fail to "accurately reflect[] the real-world bargaining" dynamics of the parties, as the law requires. *Exmark*, 879 F.3d at 1349; *Lucent*, 580 F.3d at 1325. Because he has no answer

for the unprecedented exigencies Moderna faced at the hypothetical negotiation, Dr. Vellturo ignores them entirely—and suggests the law requires the jury to do the same—by relying on a concept of "economic hold-up." His "'hold-up' opinion ignores the facts at the time of the hypothetical negotiation and incorrectly applies Federal Circuit law." *Orexo AB v. Actavis Elizabeth LLC*, 2019 WL 10060475, at *2 (D. Del. Mar. 19, 2019). It should thus be excluded.

It is beyond dispute that Moderna was subject to significant time pressure at the hypothetical negotiation (May 31, 2020), when it was planning "the fastest and largest drug launch in history." Ex 15 (Moderna 5-year plan) at -961. Its leadership "bet the entire company on something that at that point had not yet been proven in a pivotal clinical trial, phase 3 clinical trial." Ex 16 (Hoge Tr.) 92:13-93:16. This context informs "what it would have been worth to the defendant, as it saw things at the time, to obtain the authority to use the patented technology, considering the benefits it would expect to receive from using the technology and the alternatives it might have pursued." *Carnegie Mellon*, 807 F.3d at 1304. As Dr. Vellturo put it, "time was of the essence, as companies raced to be the first to market in order to slow the spread of the pandemic and meet the massive demand for a vaccine." Ex 1 (Vellturo) ¶ 277.

Nevertheless, Dr. Vellturo repeatedly asserts that timing pressure *cannot be considered* in calculating a reasonable royalty, claiming that "*any* consideration of the time to implement these same alternatives, as it relates to *any* time pressure with respect to the Hypothetical Negotiation date, is irrelevant because it reflects a notion of hold-up, as opposed to the proper isolation of the value associated with the Claimed Invention." Ex 1 (Vellturo) ¶¶ 265; 374. That misstates the law by misapplying a theory limited to Standard Essential Patent ("SEP") cases. *Orexo*, 2019 WL 10060475, at *2. Applying the theory outside of that context contradicts black letter law, which holds that an infringer is likely to pay more at a hypothetical negotiation "if avoiding the patent

would be difficult, expensive, and *time-consuming*." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1334-35 (Fed. Cir. 2015); *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1376 (Fed. Cir. 2017) ("A price for a hypothetical license may appropriately be based on consideration of the 'costs and *availability* of non-infringing alternatives.'"). In SEP cases, by contrast, "special apportionment issues" necessitate adjusting the *Georgia-Pacific* analysis. *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1231-32 (Fed. Cir. 2014). That is because when patented technology is part of an industry standard, the "technology is not always used because it is the best or the only option; it is used because its use is necessary to comply with the standard." *Id.* at 1233. As Dr. Vellturo explains, it is important that the "reasonable royalty analyses in SEP damages contexts reflect the *incremental benefit* of the patented invention *rather than* any purported value associated with the patentee's ability to 'hold up' the alleged infringer" because it is "locked into using the claimed invention via its product's adoption of the relevant standard." Ex 1 (Vellturo) ¶ 345.

This is not a SEP case. Ex 4 (Vellturo Tr.) 71:16-18. No external standard exists or creates value here—the value comes from Moderna's choice to use the patented technology, rather than seek a non-infringing alternative, at the precise moment when time was of the essence. But Dr. Vellturo nevertheless insists that the reasonable royalty analysis cannot incorporate Moderna's lack of feasible alternatives because "the general principle that reasonable royalty damages are meant to reflect the 'footprint of the patent in the marketplace' carries over to patent damages more generally." Ex 1 (Vellturo) ¶ 346. That is not the law. "Hold-up" is "limited to the narrow situation where a patentee could demand a royalty in excess of a reasonable royalty *because a standard setting organization requires an entire industry to use patented technology* to foster compatibility among devices." *Orexo*, 2019 WL 10060475, at *2. When an external standard dictates the technology to use, an infringer may have other alternatives but cannot use them

because it is "locked" into the standard. In that context, the inability to design around does not speak to the value of that technology but instead reflects the value of complying with the standard. Absent such an externally imposed standard, the lack of feasible alternatives speaks directly to the invention's value. *AstraZeneca*, 782 F.3d at 1334-35. The "costs and availability of non-infringing alternatives" are thus relevant to determining the "'footprint' of the invention." *Prism Techs.*, 849 F.3d at 1376. That Moderna "did not have a non-infringing alternative formulation ready and waiting ... is one of the most salient features of the negotiating dynamic in this case and may not now be ignored." *Astrazeneca AB v. Apotex Corp.*, 985 F. Supp. 2d 452, 501 (S.D.N.Y. 2013) (finding hold-up theory "simply inapplicable here, as the Patents do not cover a standard technology"), *aff'd in pertinent part*, 782 F.3d at 1335.

Dr. Vellturo not only ignores this legally mandated aspect of the hypothetical negotiation, he intends to tell the jury it must ignore it too. Ex 1 (Vellturo) ¶ 265. That provides another ground for exclusion. *Nursing Home*, 128 F.4th 146 at 162. Allowing Dr. Vellturo to advance his hold up theory would both impermissibly advise the jury it should ignore the absence of non-infringing alternatives and suggest, improperly, that Plaintiffs are wrongdoers seeking to "hold up" Moderna. Even though the hypothetical negotiation occurs between "willing parties [that] would have executed a license agreement," *Lucent*, 580 F.3d at 1325, Dr. Vellturo uses inflammatory language to conflate consideration of the absence of alternatives with Genevant "leverag[ing] a global health catastrophe as a bargaining tactic," which he says would mean "the number of [COVID-19] fatalities would likely have been even larger." Ex 1 ¶ 25 & n.19.

The Court's gatekeeping function requires shielding the jury from such opinions. *Minerva Surgical, Inc. v. Hologic, Inc.*, 2021 WL 3048447, at *6 (D. Del. July 20, 2021). Dr. Vellturo should not be permitted to offer his "hold-up" opinion or otherwise testify that the jury can ignore

the lack of time Moderna had to develop a non-infringing alternative.

C. Dr. Vellturo's Deficient Non-Infringing Alternative Analysis Merits Exclusion

A "core economic question" in the hypothetical negotiation is comparing "non-infringing alternatives" with the "*anticipated* ... profit-making potential" of using the patented technology. *Aqua Shield v. Inter Pool Cover Team*, 774 F.3d 766, 770 (Fed. Cir. 2014). *Georgia-Pacific* factor nine requires consideration of the "utility and advantages of the patent" over any alternatives "that had been used for working out similar results." *Georgia-Pac. Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970). Here again, Dr. Vellturo's opinions on this core issue fail. He presents precisely the type of generalized discussion of unspecified alternatives that courts find legally insufficient. And his attempt to paper over that failure by pointing to Plaintiffs' 13 other licenses lacks any basis or support. Each of these errors separately merits exclusion.

1. Dr. Vellturo cannot rely on unspecified alternative formulations

To establish non-infringing alternatives, the "proposed alternatives [must] be specifically noted, [and] their availability and acceptability must also be substantiated with record evidence." *WhereverTV, Inc. v. Comcast Cable Commc'ns*, 2022 WL 2751752, at *7 (M.D. Fla. July 14, 2022); *SynQor, Inc. v. Artesyn Techs.,* 709 F.3d 1365, 1382 (Fed. Cir. 2013). It is not enough to "speculat[e] that it might have been theoretically possible for [Moderna] to produce ... non-infringing alternatives." *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 2011 WL 197869, at *3 (E.D. Tex. Jan. 20, 2011); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (excluding "evidence that is connected to existing data only by the *ipse dixit* of the expert"). Dr. Vellturo's opinions do not meet this standard.

First, Dr. Vellturo does not *identify* any specific non-infringing alternatives. He offers only vague testimony that "Moderna had years of study and data on alternative lipid formulations outside of Spikevax® v1 and v2 Formulations, which [he] understand[s] would constitute non-

infringing alternatives based on varying molar ratios." Ex 1 ¶ 241. Failure to identify these "alternative lipid formulations" merits exclusion. *See WhereverTV*, 2022 WL 2751752, at *7.

Second, Dr. Vellturo does not address or substantiate the *availability* of any supposed alternative. He does not address the economic cost of developing an alternative or the fact that, on May 15, 2020, Moderna equated a 3-month delay with billions in foregone profits. Ex 17 (board deck) at -660. Indeed, Moderna scientists testified that "[w]hen COVID hit, at the time there was zero option for Moderna" other than to use its existing delivery platform, Ex 18 (Benenato Tr.) 68:6-69:9, and that Moderna could not make further changes to its vaccine "consistent with keeping the clinical trials going without interruption." Ex 19 (Parsons Tr.) 193:15-194:10.

Third, Dr. Vellturo does not offer the requisite evidence that any alternative would be *acceptable—i.e.*, that it does not "possess characteristics significantly different from the patented product." *Kaufman Co. v. Lantech, Inc.*, 926 F.2d 1136, 1142 (Fed. Cir. 1991). On this issue, Dr. Prud'homme suggested that the vague "alternative lipid formulations" that Dr. Vellturo alludes to would *not* have been acceptable. In his view, the formulation Moderna used in its COVID-19 vaccine—*i.e.*, the formulation accused of infringement—was the [redacted] Ex 20 (Prud'homme Tr.) 393:6-17. That is consistent with Moderna's own decision making. That Moderna did not use a formulation with a lower cationic lipid value, despite having "***strong business reasons***" to do so, Ex 2 (2017 Hoge Email), indicates this proposed alternative formulation was not an acceptable option. *CBOE v. ISE*, 2013 WL 12323444, at *2 (N.D. Ill. Mar. 7, 2013) (excluding testimony about non-infringing alternatives because infringer "contemplated this non-infringing substitute during the period of infringement"); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1353 (Fed. Cir. 1999). Because Dr. Vellturo offers no evidence that alternative lipid formulations

"would work," such alternatives are "wholly speculative and, consequently, not helpful to the trier of fact." *SRI Int'l Inc. v. Internet Sec. Sys., Inc.*, 2011 WL 5166436, at *2 (D. Del. Oct. 31, 2011).

2. Dr. Vellturo cannot testify that he addressed non-infringing alternatives through his historical licenses analysis

Dr. Vellturo tries to dodge the requirement to analyze the availability and economic cost of non-infringing alternatives by claiming the issue is addressed, inherently, through his historical licenses analysis. Dr. Vellturo opines that the 13 licenses "capture (and implicitly control for) the existence of potential non-infringing alternatives that the Genevant and Moderna would consider at the Hypothetical Negotiation." Ex 1 (Vellturo) ¶ 265. This opinion lacks the requisite support.

To begin, Dr. Vellturo's opinion is not supported by Moderna's technical experts. Dr. Vellturo does not claim to have sufficient scientific expertise to evaluate what non-infringing alternatives were available to the 13 licensees; instead, he purports to have relied on Dr. Prud'homme for that opinion. Ex 4 (Vellturo Tr.) 62:5-15, 265:4-7; Ex 1 (Vellturo) ¶ 241 n.597 (citing "Prud'homme conversation"). Yet Dr. Prud'homme disclosed no opinions about what non-infringing alternatives were available to the other licensees. Ex 21 (Prud'homme) § XI. Absent a supporting disclosure, it is not enough to cite vaguely to a "conversation" with Dr. Prud'homme. *Finalrod IP, LLC v. Endurance Lift Sols., Inc.*, 2021 WL 4906217, at *3 (E.D. Tex. Oct. 20, 2021) (excluding damages opinion relying on undisclosed opinion from technical expert); *Shure Inc. v. ClearOne, Inc.*, 2021 WL 4748744, at *1 (D. Del. Oct. 8, 2021). Indeed, Dr. Prud'homme testified that, to his knowledge, Moderna's information about alternative formulations was secret, contradicting the notion that they were equally available to the 13 licensees. Ex 20 (Prud'homme Tr.) 397:13-398:9. Without "firm factual foundation drawn from a technical expert ... the relevant portions of Dr. [Vellturo's] opinion should be stricken." *Shure*, 2021 WL 4748744, at *1.

Even if the same alternatives had been available to the 13 licensees, Dr. Vellturo makes no

attempt to show that the effects of such alternatives on those license negotiations would have been similar to their effects on the negotiation with Moderna. The 13 licenses involved products at much earlier stages of development than Moderna—with much more time to develop potential alternatives. *Supra* § III.A. For Moderna, "time was of the essence." Ex 1 (Vellturo) ¶ 277. Dr. Vellturo does not establish that any of the licensees were under similar time pressure. Indeed, he admits lacking any evidence about how the licensees "approached these negotiations," Ex 4, 136:9-12, and offers no opinion about the "economically relevant differences between the circumstances of those licenses and the circumstances of the matter in litigation," *Carnegie Mellon*, 807 F.3d at 1304. Without addressing those differences, he cannot opine that the (un)availability of non-infringing alternatives had the same effect on Moderna as for previous licensees.

* * *

When an expert performs a *Georgia-Pacific* analysis, he must "*fully* analyz[e] the *applicable* factors." *Whitserve*, 694 F.3d at 31. The circumstances of the hypothetical negotiation are inconvenient for Moderna, as it faced enormous costs and risks if it delayed its vaccine to develop an alternative with no assurance of success. Dr. Vellturo ignores these unique bargaining dynamics, replacing them with "effective rates" from agreements negotiated under vastly different circumstances. His opinions about the 13 licenses, "hold up," and non-infringing alternatives are core issues underpinning his overall opinions about a reasonable royalty, including his rebuttal of Ms. Lawton's opinions. *See* Ex 1 ¶¶ 243-244, 422, 769-770. The flaws in the "fundamental premise" of those opinions compel exclusion of both his affirmative royalty opinion and his criticisms of Plaintiffs' expert Ms. Lawton's royalty. *EcoFactor*, 137 F.4th at 1346.

IV. DR. PRUD'HOMME'S ERRONEOUS OPINIONS SHOULD BE EXCLUDED

A. Dr. Prud'homme's Doctrine of Equivalents ("DOE") Opinions Are Improper

Dr. Prud'homme's DOE opinions should be excluded for erroneously relying on unclaimed

features and not properly comparing the accused product to the Lipid Composition Patent claims.

1. Dr. Prud'homme Relied on Unclaimed Features

To dispute infringement by equivalence, Dr. Prud'homme "reli[es] on [] [unclaimed] characteristics" of the accused product, rendering his analysis legally irrelevant and "erroneous." *AquaTex Indus., Inc. v. Techniche Sols.*, 479 F.3d 1320, 1327-28 (Fed. Cir. 2007). He also "improperly compare[s] the accused product[]," including unclaimed features of the vaccine, "to the figures in the specification rather than the claim language," which compels exclusion. *Trudell Med. Int'l Inc. v. D R Burton Healthcare, LLC*, 127 F.4th 1340, 1350 n.2 (Fed. Cir. 2025).

Lipid Identity. The asserted claims recite lipids in particular amounts, and Plaintiffs assert DOE infringement over the *amount* of certain lipids. Ex 22 (Mitchell) ¶¶ 655, 683, 711. Plaintiffs do not assert DOE infringement over the *identity* of the lipids in Moderna's vaccine, including the cationic lipid ("SM-102") or the PEG-lipid, which fall within the literal scope of the claims. *Id.* at §§ XIII.C, XIII.E. Dr. Prud'homme nevertheless contends that the vaccine is not equivalent to the claims due to supposed (unclaimed) differences between the specific cationic and PEG-lipids used in the vaccine versus the illustrative lipids listed in the specification. *E.g.*, Ex 21 (Prud'homme) ¶¶ 460, 463 ("unlike the lipids identified by the [] Patents as being 'particularly useful for ... membrane fluidity' ... SM-102 does not contain [] unsaturation"), 471, 473, 478-485 ("The esters [] of the SM-102 [] make it biodegradable … which is not taught by the [] Patents."), 504, 541-542, 546-554, 573, 609 (noting "ester bonds" in Moderna's PEG-lipid), 613, 618-619 ("Moderna selected PEG-DMG-2000 for specific benefits, which distinguishes it from the conjugated lipids disclosed in the" specification). He makes similar comparisons between SM-102 and MC3, the cationic lipid in ONPATTRO, a commercial embodiment of the claims. *Id*. at ¶¶ 484, 493-501, 504, 553, 562-570, 573. These differences are legally irrelevant to DOE, which relates to lipid amount, not identity. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1293

(Fed. Cir. 2010) ("proper [DOE] inquiry" focuses on "claimed value" versus "accused value").

Manufacturing Methods. The claims recite compositions and are agnostic as to manufacturing method, Ex 23 (Anderson) 288:22-24. Dr. Prud'homme nonetheless disputes DOE infringement based on the supposed benefits of Moderna's manufacturing process. He argues that Moderna's "[redacted]) defeat DOE. Ex 21 (Prud'homme) ¶¶ 462, 598, 610-612, 614-617, 620, 627-628, 678, 691 ("because the claimed compositions ... are not manufactured in the same way as Moderna's COVID-19 vaccine ... the non-cationic lipids do not perform the same functions in the same way"), 693 ("Moderna uses a fundamentally different manufacturing process"), 736. He opines similarly about other supposedly "innovative and proprietary" aspects of Moderna's manufacturing [redacted]). *Id.* at ¶¶ 689-690, 694.

Payload and Administration. The asserted claims do not require, and the invention is not limited to, siRNA or a specific mode of administration. *E.g.*,'435 patent, 10:26-36, 25:20-24. Nevertheless, Dr. Prud'homme repeatedly contends that the "Patents [] are directed to intravenous delivery of siRNA." Ex 21 (Prud'homme) ¶ 573; *accord id.* at ¶¶ 466, 477, 488, 546, 549, 557, 603-604, 607, 609, 623. He relies on these (unclaimed) features to dispute DOE, stating "Moderna's SPIKEVAX® delivers mRNA intramuscularly, unlike the [] Patents." *Id.* at ¶ 573; *accord id*. at ¶¶ 471, 478, 487, 501-504, 541-542, 556, 570-571, 603, 609, 622, 627, 675, 693.

* * *

Dr. Prud'homme's DOE testimony concerning limitations not "recited in the claims" is "irrelevant [and] would confuse the jury," *Minerva*, 2021 WL 3048447, at *8-9, and compels exclusion, *Trudell*, 127 F.4th at 1350 (allowing infringement testimony "abused [] discretion").

2. Dr. Prud'homme's Lipid Molar Ratio Comparisons Were Improper

Dr. Prud'homme also disputes infringement by asserting that Moderna's vaccine is not

equivalent to the lipid mol % of only certain embodiments within the claims. That is legally wrong and will confuse the jury, thereby compelling exclusion. *Nursing Home*, 128 F.4th at 162.

"The proper [DOE] inquiry is whether the accused value is insubstantially different from the claimed value." *Adams*, 616 F.3d at 1293. DOE infringement is established where the accused product is equivalent to ***any*** part of the claimed range, including its ***end point***. *Id*. (claimed range is "at least 3500 hr*ng/mL," DOE infringement where 3493.38 hr*ng/mL is equivalent to 3500 hr*ng/mL); *Par Pharm., Inc. v. Hospira, Inc.*, 420 F. Supp. 3d 256, 278 (D. Del. 2019), *aff'd*, 835 F. App'x 578 (Fed. Cir. 2020) (claimed range is "about 6 to 8 mg/ml," DOE infringement where 9 mg/mL is equivalent to 8 mg/ml); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 114 F.3d 1161, 1164 (Fed. Cir. 1997) (claimed range is "approximately 6.0-9.0," DOE infringement where pH of 5.0 is equivalent to 6.0). Thus, while challengers are precluded from using embodiments to *defeat* infringement, as they do not "represent[] the entire scope of the claimed invention," *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1370 (Fed. Cir. 2002), equivalence to a literally infringing embodiment is "sufficient to *establish* [DOE] infringement," *WCM Indus. v. IPS Corp.*, 721 F. App'x 959, 968-69 (Fed. Cir. 2018); *Supernus Pharms. Inc. v. Actavis Inc.*, 2016 WL 527838, at *17 (D.N.J. Feb. 5, 2016), *aff'd*, 665 F. App'x 901 (Fed. Cir. 2016).

Plaintiffs assert that the mol% of the accused product (specifically, particles reflecting the aggregate, unfractionated lipid molar ratios of the vaccine) are equivalent to the claimed ranges, including particles at the endpoints of the ranges (*i.e.*, 50 mol% cationic, 49.5 mol% non-cationic, and 2 mol% PEG-lipid). Moderna largely endorses this assertion. For example, the experts and "Moderna scientists confirmed that decreasing cationic lipid SM-102 from 50 to 48.0 mol%"—*i.e.*, from the endpoint of the claimed 50-65 range to a value asserted to infringe under DOE—"did not significantly affect immunogenicity, potency, or stability" of the vaccine, Ex 21 ¶¶ 555, 486,

and they found similarly for PEG, *id.*, and non-cationic lipids, *id.* at ¶ 692. Moderna advised FDA that increasing the PEG-lipid from 1.5 (within the claims) to 2.5 mol% (alleged to be equivalent) did "not impact [the vaccine's] quality attributes," Ex 22 (Mitchell) ¶ 724; [redacted] Moderna's corporate representative confirmed, Ex 22 (Mitchell) ¶ 725; Ex 25 (Stability Study) at 2, 4. And Dr. Prud'homme does not dispute that batches of Moderna's vaccine with measured lipid molar ratios falling slightly outside of the literal claims are equivalent to batches with ratios within the claims, contending only (and legally incorrectly) that this comparison was improper. Ex 21 (Prud'homme) ¶ 467; *WCM*, 721 F. App'x at 968-69; *Supernus*, 2016 WL 527838, at *17.

Unable to dispute equivalence under the proper legal framework, Dr. Prud'homme resorts to legally inapt comparisons. For example, he relies on Plaintiffs' experiments comparing the "1:57" formulation (57 mol% cationic lipid target) to formulations with 30 or 40 mol% cationic lipid. *E.g.*, Ex 21 (Prud'homme) ¶¶ 488-489, 555, 557, 621, 623, 686, 692. These experiments (and his resulting analysis) do not address either side of the legally mandated inquiry: (1) the endpoint of the claims (50, not 57) and (2) the accused equivalent (45 or 48 or 48.5, not 30 or 40).[2] *Adams*, 616 F.3d at 1293; *Par*, 420 F. Supp. 3d at 278; *Warner-Jenkinson*, 114 F.3d at 1164. Where the accused value is equivalent to an endpoint of the range, the law mandates a finding of DOE. *Id.* Dr. Prud'homme's inapt comparisons thus cannot negate a finding of DOE—at most, they support the irrelevant propositions that embodiments within the claim are not equivalent to each other, and that other, non-accused values are not equivalent. This DOE evidence is "irrelevant

[2] The same is true of testimony relying on (1) Moderna's comparisons of values (such as 38.8 mol % cationic lipid) not alleged to be equivalent, *e.g.*, Ex 21 ¶ 536 (citing Ex 26 (MRNA-GEN-00533651) at -662), and (2) comparisons between non-endpoints of a range—such as 1.5 mol% PEG lipid (claimed range is 0.5-2 mol%)—to values outside the range, Ex 21 ¶ 598, as Moderna's witnesses conceded equivalence to the claim *endpoint* of 2 mol%, Ex 22 (Mitchell) ¶ 440.

[and] would confuse the jury," thereby compelling exclusion. *Minerva*, 2021 WL 3048447, at *9.

B. Dr. Prud'homme's Reverse DOE Opinions Should Be Excluded

The Federal Circuit has "never affirmed a decision finding noninfringement based on the reverse doctrine of equivalents" (RDOE)—an "anachronistic exception" that likely has been "subsumed by [] §112." *Steuben Foods, Inc. v. Shibuya Hoppmann Corp.*, 127 F.4th 348, 356-357 (Fed. Cir. 2025). RDOE may apply where, despite literal infringement, "a device is so far changed in principle from a patented article that it performs the same or similar function in a substantially different way." *Id*. at 356. Like DOE, reliance on unclaimed features "completely misconstrue[s] the [RDOE] inquiry." *Phillips Petroleum Co. v. U.S. Steel Corp*., 673 F. Supp. 1278 (D. Del. 1987) (holding toughness irrelevant), *aff'd*, 865 F.2d 1247 (Fed. Cir. 1989); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1123 (Fed. Cir. 1985) (one who uses a claimed structure in a different way from "a specification-described embodiment … does not [] escape infringement"). Dr. Prud'homme's RDOE opinions are based on the same unclaimed features as his DOE analysis, *supra* IV.A.1., which he incorporates by reference to dispute infringement based on Moderna's purported "proprietary manufacturing process, ionizable lipid SM-102, and LNPs specifically adapted for mRNA." Ex 21 ¶¶ 866-868. These improper opinions should be excluded.

C. Dr. Prud'homme's Intermediate Particle Opinions Should Be Excluded

In addition to the final drug product, the intermediate particles formed during the vaccine manufacturing process infringe Plaintiffs' patents. Ex 22 (Mitchell) ¶¶ 615-617; D.I. 612 at ¶ 30.

Dr. Prud'homme's opinions disputing infringement by the intermediate particles commit "one of the cardinal sins of patent law" by "reading a limitation" into the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) (en banc). Moderna and its experts acknowledge that the claims do not include a stability requirement. *E.g.*, D.I. 556 (Moderna SJ Response) at 19-20 ("both Drs. Prud'homme and Anderson agreed that the claims did not require unclaimed

properties," including stability); Ex 27 (Anderson Reply) ¶ 194. In addition, Judge Goldberg already rejected Moderna's attempt to foreclose Plaintiffs' intermediate infringement theory, D.I. 266 at 14, finding that the Lipid Composition claims "read[] on *any product at any time* that contains the claimed proportions of ingredients," *id*. at 10. Yet Dr. Prud'homme disputes infringement of the intermediate particles based on (unclaimed) stability and duration limitations. *E.g.*, Ex 21 (Prud'homme) ¶¶ 717 (disputing infringement because the particles allegedly exist for [redacted]"), 723-725 ("instability" of the intermediate precludes infringement because the claims "are directed to stable particles"), 730, 737.

Infringement testimony relying on imported limitations is "methodological[ly] unsound[]" and compels exclusion, *Trudell*, 127 F.4th at 1350, as it is "unreliable and unhelpful to the [jury]," *Personalized User Model, L.L.P. v. Google Inc.*, 2014 WL 807736, at *1 (D. Del. Feb. 27, 2014).

D. Dr. Prud'homme's Improper Enablement Opinions Should be Excluded

As Plaintiffs explained—and Moderna effectively conceded—Dr. Prud'homme's non-enablement opinions include the three categories of legal errors set forth below. D.I. 524, 12-25; D.I. 557, 15-24; D.I. 589, 4-10. Dr. Prud'homme's opinions identified in D.I. 590-1, 590-2 "proffer ... markedly incorrect law" and are inadmissible under Rule 702. *Hebert*, 99 F.3d at 1117.

Unclaimed Features. Moderna conceded that Dr. Prud'homme's enablement opinions improperly relied on unclaimed properties, D.I. 556 at 19, and represented that it "will not present" such opinions, D.I. 557 at 17. But despite Moderna's representation, it still relies on the erroneous testimony. D.I. 591 at 10-11; D.I. 592, response to ¶ 74 (citing unclaimed features like size). Enablement of unclaimed features is inapt and excludable. *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006); D.I. 524 at 13-14, 18-19.

Alternative Manufacturing Modes. Moderna concedes that the enablement requirement is met if the specification enables any mode of making and using the invention, yet argues, through

Dr. Prud'homme, that manufacturing methods not described in the '651 patent somehow demonstrate that the claims are non-enabled. D.I. 557 at 19-21. Moderna's arguments on this issue are "legally irrelevant," *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998), and the testimony should be excluded, D.I. 589 at 7; D.I. 524 at 20-21.

Measurement Requirement. Dr. Prud'homme asserts non-enablement of all claims due to alleged difficulties measuring infringement, but the law is clear that this criticism is irrelevant to enablement and must be excluded. D.I. 524 at 23-25. Moderna does not dispute this legal standard but instead argues that measurement is required to make the invention. D.I. 557 at 21-22; D.I. 589 at 7-8. Not so. Numerical limitations in claims "describe a feature of the claimed invention, not a measurement requirement." *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 477 F. Supp. 3d 306, 354 (D. Del. 2020), *aff'd*, 858 F. App'x 359 (Fed. Cir. 2021); D.I. 524 at 23. Dr. Prud'homme's opinions are plainly about proving infringement. D.I. 589 at 7-10; D.I. 524 at 23-25. In addition, he improperly incorporates testimony about measuring encapsulation to attack the Lipid Composition Patents, which recite no such limitation. D.I. 589 at 8; D.I. 557 at 21-23.

E. Dr. Prud'homme's Improper Indefiniteness Opinions Should be Excluded

As Plaintiffs have explained, Dr. Prud'homme's indefiniteness opinions also include improper arguments about the POSA's ability to assess infringement. D.I. 561 at 14-20; *e.g.*, Ex 29, §§ X.A.1, XI.A.1; Ex 30, §§ VI.A.1, VIII.A.1. *SmithKline* and its progeny make clear that difficulty in measuring infringement is irrelevant to indefiniteness. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340-41 (Fed. Cir. 2005); D.I. 561 at 14-15; D.I. 611 at 5-7. Moderna's attempts to misread *SmithKline* and cite non-analogous cases where testing implicated disputes about *claim scope*, D.I. 596 at 11-13, are unavailing. Dr. Prud'homme's testing opinions do not address a claim scope dispute (there is none). D.I. 611 at 7-10; D.I. 612 ¶¶ 17, 40-41, 44. His opinions go to infringement and should be excluded as to indefiniteness.

V. DR. ANDERSON'S HINDSIGHT OPINIONS SHOULD BE EXCLUDED

Dr. Anderson, Moderna's sole obviousness expert, admits that he assessed obviousness impermissibly "through the lens" of the Patents-in-Suit, instead of the prior art. Ex 23 (Anderson Tr.), 95:1-14, 168:25-169:11. That was no passing remark, but rather the analysis Dr. Anderson was asked to and did perform, as he testified time and again in his report and at deposition. *E.g.*, *id.* at 121:4-122:11, 136:5-18, 172:17-24; Ex 28 (Anderson) ¶ 59 ("[F]or purposes of considering prior art disclosures of nucleic acids ... I view the prior art through the lens of the '651 patent."). Dr. Anderson's obviousness opinions therefore must be excluded because they would "not [be] helpful to a lay jury in avoiding the pitfalls of hindsight that belie a determination of obviousness"—they instead would lead the jury directly into that pitfall. *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373-74 (Fed. Cir. 2008).

"The inventor's own path itself never leads to a conclusion of obviousness; that is hindsight." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012). Precedent and statute thus foreclose using the asserted "patent itself as [a] roadmap for putting together" the prior art like "pieces of a jigsaw puzzle." *InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014); 35 U.S.C. § 103(a) ("Patentability shall not be negatived by the manner in which the invention was made."). Obviousness instead turns on "whether the claimed invention would have been obvious in view of the *prior art*," without the benefit of the claimed inventions, *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015), and "requires finding both [1] that a skilled artisan would have been motivated to combine the teachings of the prior art and [2] that the skilled artisan would have had a reasonable expectation of success in doing so," *In re Stepan*, 868 F.3d 1342, 1345-46 (Fed. Cir. 2017).

Rather than evaluate the prior art ex ante, as precedent requires, Dr. Anderson admitted candidly and repeatedly that his "task was to analyze the prior art as a POSA *through the lens of*

the molar ratio patents" and the '651 patent. Ex 23, 168:25-169:11, 95:1-14; *id.* at 136:5-18, 172:17-24; Ex 28 ¶ 59. Because his hindsight-based approach is simply "not evidence of obviousness," *Zoltek Corp. v. United States*, 815 F.3d 1302, 1311 (Fed. Cir. 2016), his obviousness opinions should be excluded as unhelpful to the jury and irrelevant, *Innogenetics*, 512 F.3d at 1373.

Lipid Composition Patents. The Lipid Composition Patent claims recite particles having certain molar ratio ranges of various lipid components. Since it is undisputed that no single prior art reference teaches these ranges, Dr. Anderson asserts that the POSA would "mix and match the molar percentages" of four alleged prior-art formulations, each having different molar ratios of the four lipid components—(1) 48:40:10:2, (2) 30:20:48:2, (3) 50:20:28:2, and (4) 40:10:48:2 (cationic:phospholipid:cholesterol:PEG-lipid)—to arrive at a ratio of 48:10:40:2 or 50:10:38:2. Ex 28 ¶¶ 985-986. But fatally, just as in *InTouch*, Dr. Anderson "fail[s] to provide the glue to combine these" formulations or offer "what reason or motivation [the POSA] would have had to" combine them. 751 F.3d at 1348-49. His arbitrary "mix and match" approach (Ex 28 ¶ 986) lacks any rationale for *how* and *why* the POSA would combine these formulations to arrive at the claims and thus cannot support obviousness. *Id.* For example, he offers no "articulated reasoning" to select, among his handpicked formulations, 50 or 48 mol% cationic lipid rather than 30 or 40 mol%, or 10 mol% phospholipid instead of 40 or 20 mol%. 751 F.3d at 1351. To fill this prior art gap, he invokes the "Molar Ratio Patents themselves" and the "invention documents produced by Plaintiffs," which are undisputedly not prior art. Ex 28 ¶¶ 987-991; Ex 27 (Reply) ¶ 152.

At his deposition, Dr. Anderson testified that he could not "remember the thought process[]" behind combining the four formulations, Ex 23, 235:14-236:4, 234:24-235:13, and admitted that he "select[ed] the lipid molar ratio formulations" from his report by viewing "the prior art ... through the lens of the molar ratio patents"—a "lens" that did not exist in the prior art.

Id. at 169:4-11; *see also id.* at 95:11-14, 190:2-14, 224:4-19. That approach infected the entirety of his opinions. *Id.* at 167:25-168:24, 172:17-173:3. Using the asserted "patent itself as [a] roadmap" (or "lens") for selecting and combining the prior art is quintessential hindsight, *InTouch*, 751 F.3d at 1351, and neither Dr. Anderson's amnesia nor hindsight provides a cognizable basis for obviousness. *See Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378-79 (Fed. Cir. 2012).

Precedent mandates exclusion of Dr. Anderson's obviousness opinions, "which [do] not offer any motivation for [the POSA] to combine the particular references he cites in order to practice the claim[s]," as such "vague testimony" is not "helpful to a lay jury in avoiding the pitfalls of hindsight." *Innogenetics*, 512 F.3d at 1373-74; *see Acceleration Bay, LLC v. Amazon Web Servs., Inc.*, 2024 WL 4164876, at *18 (D. Del. Sept. 12, 2024).

'651 Patent. The '651 patent requires a formulation comprising mRNA "wherein at least 70% of the mRNA in the formulation is fully encapsulated." '651 patent, claim 1. Dr. Anderson fails to articulate how the POSA reasonably would have expected to obtain 70% fully encapsulated mRNA *in view of the prior art* and instead premises his analysis entirely and impermissibly on hindsight knowledge of "the disclosures of the '651" patent." Ex 23, 136:5-13.

Reasonable expectation of success cannot be based on hindsight. In *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (Fed. Cir. 2021), the court explained that the "patent itself" could not supply a reasonable expectation of success, because the "inventor's own path itself never leads" to obviousness. Thus, obviousness could not be upheld where "only with the benefit of hindsight … would [the POSA] have had a reasonable expectation of success." *Id.*

Yet hindsight is concededly the foundation of Dr. Anderson opinions. He points to no prior-art evidence achieving 70% mRNA encapsulation using the claimed lipid components. Ex 28 ¶¶ 326, 392, 453, 512; *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019)

("the only reasonable expectation at the time of the invention was failure, not success"). Although his report asserts that prior art like Semple and Saravolac somehow provided a reasonable expectation of success, Ex 28 ¶¶ 452-453, Dr. Anderson confirmed at his deposition, expressly and repeatedly, that he again impermissibly viewed the prior art with hindsight "through the lens of the '651" patent. Ex 23, 30:25-31:9; *InTouch*, 751 F.3d at 1351. For example, he testified that his analysis of "the '651 for anticipation and obviousness ... ***considered the disclosures of the '651 to analyze the prior art***," Ex 23, 136:5-13, including—critically—for his opinion that "a POSA [would] have expected the encapsulation process of the Semple article to work with mRNA." *Id.* at 120:13-123:17 ("I performed the analysis that I was asked to do, and ***that was through the lens of the '651***."), 290:1-18 ("I analyze Saravolac in light of the '651."), 28:10-29:6, 58:10-23 (same).

This was the core of Dr. Anderson's obviousness analysis. Ex 28 ¶ 59; Ex 23, 72:1-24, 94:8-95:14, 97:12-99:11, 125:1-25, 135:23-136:22, 159:18-160:17. Over pages of testimony, Dr. Anderson could not identify any method in the prior art that the POSA could have used to achieve the claimed levels of fully encapsulated mRNA. Ex 23, 290:1-296:19 (unable to identify teaching in Saravolac to provide expectation of achieving 70% mRNA encapsulation), 30:7-33:10 (unable to identify example using Semple method with mRNA), 141:11-146:21 (unable to identify any encapsulation data in Bischoff). Rather, in each of those instances, he resorted to citing the disclosures of the '651 patent. *Id.* at 290:14-18 ("I analyze Saravolac in light of the '651"), 31:4-9 (used "lens of the '651 patent" with Semple), 143:1-10 (citing "disclosure of the '651 patent" with Bischoff). Because Dr. Anderson's opinions on reasonable expectation of success are premised entirely on hindsight, his obviousness opinions on the '651 patent provide no help "to a lay jury in avoiding the pitfalls of hindsight" and thus must be excluded. *Innogenetics*, 512 F.3d at 1373-74; *see Strathclyde*, 17 F.4th at 165; *Stepan*, 868 F.3d at 1345-46.

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Dated: December 16, 2025